

## **REMARKS**

Claims 1-4, 6 and 13-16 are pending in this application. Claims 1-4, 6 and 13 are amended above to identify a dosing amount, and to direct the invention to a composition for inhibiting the development and metastasis of certain cancers.

Claim 5 is cancelled from the application.

Claims 14-16 are newly added to the application.

No new matter is added to the application by these claim amendments.

The examiner's specification and claim rejections are overcome or they are traversed as set forth below.

### **I. THE ANTICIPATION REJECTION**

#### **A. Traverse of the Rejection of Claims 1 and 3-6 Over The Kexin et al. Article**

The examiner rejected claims 1 and 3-6 for being anticipated by the Kexin et al. article. It is the examiner's position that Kexin et al. discloses the use of Shenqui Fuzheng. Moreover, it is the examiner's position that Shenqui Fuzheng includes the same components as the invention set forth in claim 1.

Independent claim 1 is amended above to direct it to compositions that inhibit the development and metastasis of colon cancer, lung carcinoma or mammary adenocarcinoma. Moreover, independent claim 1 is amended to require the administration of a composition dose of no less than 0.2 g/kg. These amendments cause claims 1, 3-4 and 6 to be novel over Kexin. In particular, the examiner acknowledges that Kexin does not disclose the use of Shenqui Fuzheng for the treatment of colon cancer, lung carcinoma or mammary carcinoma. Therefore, the amendment of claim 1 above to direct it to composition for treating these cancers causes the pending application claims 1, 3-4 and 6 to be novel over Kexin et al. Moreover, the claimed dosing range is believed to render the pending application claims patentable of Kexin as well.

For at least these reason, the examiner's rejection of claims 1 and 3-6 for lack of novelty over Kexin et al. should be withdrawn.

#### **B. Traverse of the Rejection of Claims 1-6 Over Chen et al.**

The examiner rejected claims 1-6 and new claim 13 for being anticipated by Chen et al. (US 2004/0105902). It is the examiner's position that Chen et al. discloses a composition for treating

prostate cancer wherein the compositions comprises a therapeutic effective amount of *Astragalus radix* and *Codonopsis pilosulae radix*.

The amendment of independent claims 1 and 2 above to direct them to compositions for inhibiting the development of certain kinds of cancers causes pending application claims 1-4 and 6 to be novel over Chen et al. As the examiner acknowledged in the latest Office Action, Chen et al. does not specifically disclose composition that can be used for the treatment of colon cancer, lung carcinoma or mammary carcinoma.” The amended claims, now all directed to compositions for inhibiting the development of colon cancer, lung carcinoma or mammary carcinoma are novel over Chen et al. Moreover, the claimed dosing range is also believed to cause the pending application claims to be novel over Chen et al. as well.

## **II. THE 112 2<sup>nd</sup> PARAGRAPH REJECTION**

The examiner rejected claims 1-6 and 13 under 35 USC § 112, second paragraph for being indefinite. The examiner’s objections have been overcome as set forth below.

The examiner’s rejection of the claims for being mixed composition and method claims is overcome by amending the claims to make it clear that they are composition claims.

The examiner’s rejection of claim 13 because it is unclear which elements are excluded from the transitional phrase “consisting essentially of” is believed to be without merit. The term “consisting essentially of” used preceding a list of ingredients means that the composition includes the listed ingredients and is open to unlisted ingredients that do not materially effect basic and novel properties of the invention. *PPG Indus. V. Guardian Indus. Corp.*, 156 F.3d 1351, 1353, 48 USPQ2d 1351, 1353-4 (Fed. Cir. 1998). To determine the ingredients included versus excluded from the claims by this language, one must read the claims in light of the specification. *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. 1989). There is no requirement that the specification include an express teaching of what is included and excluded by the “consisting essentially of” language.

One skilled in the art at the time of the invention upon reading the specification would readily understand that the two ingredients listed after the term “consisting essentially of” are the active ingredients that achieve the claimed inhibiting development and metastasis of the claimed method. Moreover, one skilled in the art would understand that the claims would not encompass

compositions that include ingredients, other than the two listed ingredients that materially effect the development and metastasis of the listed cancers and carcinomas. For at least this reason, the examiner's rejection of claim 13 under 35 USC § 112 second paragraph is believed to without merit and should be withdrawn because the specification clearly apprises one skilled in the art at the time of the invention what compounds are covered by the consisting essentially of language and why.

### **III. THE 112, 1<sup>st</sup> PARAGRAPH REJECTIONS**

#### **A. The Rejection Of Claim 13**

The examiner rejected claim 13 under 35 USC § 112 first paragraph for failing to comply with the written description requirement. In particular, the examiner takes the position that the applicant has not pointed to any disclosure that teaches which elements would alter the basic novel characteristics of the invention and therefore potentially excluded from the invention.

As discussed in Section II above, the boundaries of the claims proceeded by the term "consisting essentially of" are dictated by considering the claims in light of the specification. As indicated above, the specification sufficiently apprises one skilled in the art what the novel properties of the invention are and what compounds are included in the claims that affect those novel properties. In particular, the novel property of the invention is directed to a method for treating specific cancers using a specific dose of a composition including two active ingredients. One of ordinary skill in the art would understand from the specification and claims that adding an ingredient to the dosed composition that impacts the "inhibiting development and metastasis of" the recited cancers would fall outside of the scope of the claims. For at least this reason, the examiner's rejection of claim 13 under 35 USC § 112 first paragraph should be withdrawn.

#### **B. The Rejection Of Claims 1-6 And 13**

The examiner rejected claims 1-6 and 13 under 35 USC § 112 first paragraph because the specification does not reasonably provide enablement for composition for inhibiting carcinogenesis of colon cancer, lung carcinoma or mammary adenocarcinoma. In particular, it is the examiner's position that while the specification provides examples for treating metastasis and inhibition of tumor growth, the specification includes no correlation between the claimed

composition and inhibiting carcinogenesis, *i.e.*, preventing cancer.

The examiner's rejection of claims 1-6 and 13 is overcome by amending the claims to direct them to methods for "inhibiting development and metastasis of [three listed cancers]". This causes the claims to be more commensurate in scope to the specification description and examples and requires little or no additional experimentation on part of persons skilled in the art to practice the invention. For this reason, the amended claims are believed to overcome the examiner's § 112 first paragraph rejection.

#### **IV. NEW CLAIMS 14-16**

Claims 14-16 are newly added to the application. Claim 14 narrows the scope of claim 1 by using the term "consisting essentially of" in reference to the composition administered in the method of claim 1. Claims 15 and 16 narrow claim 1 even further by defining the administered composition using the phrase "consists of". Claims 14-16 are patentable by virtue of their dependence upon claim 1 and they are independently patentable by virtue of their narrowing of claim 1 in a manner that causes the claims to be novel and patentable over the cited prior art.

#### **CONCLUSION**

Claims 1-4, 6 and 13-16 are believed to patentable for the reasons indicated above. Favorable reconsideration and allowance of all pending application claims is, therefore, courteously solicited.

McDonnell Boehnen Hulbert & Berghoff LLP

Date: July 10, 2007

By: /A. Blair Hughes/  
A. Blair Hughes  
Reg. No. 32,901